

# Interim Clinical Guidance for the Treatment of Monkeypox

## 2022 U.S. Monkeypox Cases

- CDC is tracking multiple cases of monkeypox that have been reported in several countries that don't normally report monkeypox, including the United States.
- CDC is urging healthcare providers in the U.S. to be alert for patients who have rash illnesses [consistent with monkeypox](#).
- CDC is working with state and local health officials to identify people who may have been in contact with individuals who have tested positive for monkeypox, so they can monitor their health.
- Monkeypox is rare and does not spread easily between people without close contact. The threat of monkeypox to the general U.S. population remains **LOW**.

Many individuals infected with monkeypox virus have a [mild, self-limiting disease course](#) in the absence of specific therapy. However, the prognosis for monkeypox depends on multiple factors such as previous vaccination status, initial health status, concurrent illnesses, and comorbidities among others. People who should be considered for treatment following consultation with CDC might include:

- People with severe disease (e.g., hemorrhagic disease, confluent lesions, sepsis, encephalitis, or other conditions requiring hospitalization)
- People who may be at high risk of severe disease:
  - People with immunocompromise (e.g., human immunodeficiency virus/acquired immune deficiency syndrome infection, leukemia, lymphoma, generalized malignancy, solid organ transplantation, therapy with alkylating agents, antimetabolites, radiation, tumor necrosis factor inhibitors, high-dose corticosteroids, being a recipient with hematopoietic stem cell transplant <24 months post-transplant or ≥24 months but with graft-versus-host disease or disease relapse, or having autoimmune disease with immunodeficiency as a clinical component)<sup>1</sup>
  - Pediatric populations, particularly patients younger than 8 years of age<sup>2</sup>
  - Pregnant or breastfeeding women<sup>3</sup>
  - People with a history or presence of atopic dermatitis, people with other active exfoliative skin conditions (e.g., eczema, burns, impetigo, varicella zoster virus infection, herpes simplex virus infection, severe acne, severe diaper dermatitis with extensive areas of denuded skin, psoriasis, or Darier disease [keratosis follicularis])
  - People with one or more complications (e.g., secondary bacterial skin infection; gastroenteritis with severe nausea/vomiting, diarrhea, or dehydration; bronchopneumonia; concurrent disease or other comorbidities)<sup>4</sup>
- People with monkeypox virus aberrant infections that include its accidental implantation in eyes, mouth, or other anatomical areas where monkeypox virus infection might constitute a special hazard (e.g., the genitals or anus)

## Medical Countermeasures Available for the Treatment of Monkeypox

Currently there is no specific treatment approved for monkeypox virus infections. However, antivirals developed for use in patients with smallpox may prove beneficial. The following medical countermeasures are currently available from the Strategic National Stockpile (SNS) as options for the treatment of monkeypox:

- Tecovirimat (also known as TPOXX) is an antiviral medication that is [approved by the United States Food and Drug Administration \(FDA\)](#)  [\[PDF - 24 pages\]](#)  for the treatment of smallpox in adults and children. CDC holds an expanded access protocol (sometimes called "compassionate use") that allows for the use of stockpiled tecovirimat to

treat monkeypox during an outbreak. Tecovirimat is available as a pill or an injection. For children who weigh less than 28.6 pounds, the capsule can be opened and medicine mixed with semi-solid food.

- Cidofovir (also known as Vistide) is an antiviral medication that is [approved by the FDA](#)  [\[PDF – 6 pages\]](#)  for the treatment of cytomegalovirus (CMV) retinitis in patients with Acquired Immunodeficiency Syndrome (AIDS). CDC holds an expanded access protocol that allows for the use of stockpiled Cidofovir for the treatment of orthopoxviruses (including monkeypox) in an outbreak.
- Vaccinia Immune Globulin Intravenous (VIGIV) is [licensed by FDA](#)  for the treatment of complications due to vaccinia vaccination including eczema vaccinatum, progressive vaccinia, severe generalized vaccinia, vaccinia infections in individuals who have skin conditions, and aberrant infections induced by vaccinia virus (except in cases of isolated keratitis). CDC holds an expanded access protocol that allows for the use of stockpiled VIGIV for the treatment of orthopoxviruses (including monkeypox) in an outbreak.

Brincidofovir (also known as Tembexa) is an antiviral medication that was [approved by the FDA](#)  [\[PDF – 21 pages\]](#)  on June 4, 2021 for the treatment of human smallpox disease in adult and pediatric patients, including neonates. CDC is currently developing an EA-IND to help facilitate use of Brincidofovir as a treatment for monkeypox. However, Brincidofovir is not currently available from the SNS.

State and territorial health authorities can direct their requests for medical countermeasures for the treatment of monkeypox to the CDC Emergency Operations Center (770-488-7100).

## References

- <sup>1</sup>Petersen BW, Harms TJ, Reynolds MG, Harrison LH. Use of Vaccinia Virus Smallpox Vaccine in Laboratory and Health Care Personnel at Risk for Occupational Exposure to Orthopoxviruses — Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2015. *MMWR Morb Mortal Wkly Rep* 2016;65:257–262. DOI: <http://dx.doi.org/10.15585/mmwr.mm6510a2>
- <sup>2</sup>Jezek Z, Szczeniowski M, Paluku KM, Mutombo M. Human monkeypox: clinical features of 282 patients. *J Infect Dis.* 1987 Aug;156(2):293-8. doi: 10.1093/infdis/156.2.293. PMID: 3036967.
- <sup>3</sup>Cono J, Cragan JD, Jamieson DJ, Rasmussen SA. Prophylaxis and treatment of pregnant women for emerging infections and bioterrorism emergencies. *Emerg Infect Dis.* 2006 Nov;12(11):1631-7. doi: 10.3201/eid1211.060618. PMID: 17283610; PMCID: PMC3372351. Mbala PK, Huggins JW, Riu-Rovira T, Ahuka SM, Mulembakani P, Rimoin AW, Martin JW, Muyembe JT. Maternal and Fetal Outcomes Among Pregnant Women With Human Monkeypox Infection in the Democratic Republic of Congo. *J Infect Dis.* 2017 Oct 17;216(7):824-828. doi: 10.1093/infdis/jix260. PMID: 29029147.
- <sup>4</sup>Ogoina D, Iroezindu M, James HI, Oladokun R, Yinka-Ogunleye A, Wakama P, Otike-Odibi B, Usman LM, Obazee E, Aruna O, Ihekweazu C. Clinical Course and Outcome of Human Monkeypox in Nigeria. *Clin Infect Dis.* 2020 Nov 5;71(8):e210-e214. doi: 10.1093/cid/ciaa143. PMID: 32052029.